ANDA 75-810

August 31, 2001

Barr Laboratories, Inc.
Attention: Christine Mundkur
2 Quaker Road
P.O. Box 2900
Pomona, New York 10970-0519

Dear Madam:

This is in reference to your abbreviated new drug application dated February 25, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fluoxetine Hydrochloride Tablets, 10 mg (base).

Reference is also made to your amendments dated March 9, April 27, May 30, July 19, July 24, and August 9, 2001.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product). The determination is subject to change on the basis of new information that may come to our attention.

The listed drug product referenced in your application, Prozac Tablets 10 mg (base) of Eli Lilly & Co., is subject to a period of patent protection which expires on June 2, 2004, (U.S. Patent No. 4,626,549 [the '549 patent]). Your application contains a Paragraph IV Certification to the ‘549 patent under Section 505(j)(2)(A)(vii)(IV) of the Act. You informed us that Eli Lilly and Company initiated a patent infringement action against you in the United States District Court for the Southern District of Indiana, Indianapolis Division (Eli Lilly and Company v. Barr Laboratories Inc., Apotex Inc., and Bernard C. Sherman, Civil Action No. IP00-0850C - H/G). With regard to the

expiration of this patent, reference is made to the recent decision of the same District Court noted above (Eli Lilly and Company v. Barr Laboratories, Inc. et al., Civil Action No. IP 96-0491 C B/S) in which the court ruled that the U-84 claim (uptake of monoamines by the brain) of the '549 patent is invalid. However, the court did not find that the entire patent (i.e., including the U-154 claim for appetite disorder) to be invalid. This decision was upheld by the Court of Appeals. Thus, the '549 patent will remain listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") until patent expiry, currently June 2, 2004.

We note, however, that you have also submitted a Method of Use Statement under Section 505(j)(2)(A)(viii) of the Act addressing the U-154 (appetite disorder) claim of the '549 patent. Thus, your proposed labeling will not include the "Bulimia Nervosa" indication held by the RLD, and will be limited until patent expiry or a subsequent court decision to the "Depression" and "Obsessive-Compulsive Disorder" indications.

Furthermore, we are unable to grant final approval to this application at this time because another application for Fluoxetine Hydrochloride Tablets 10 mg (base) [ANDA 75-755 submitted by Alphapharm PTY. LTD. (Alphapharm)] containing a Paragraph IV Certification was accepted for filing by this office prior to the filing of your application. This application was approved on August 2, 2001. Consequently, Alphapharm is deemed eligible for 180-days of generic drug market exclusivity as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. Thus, final approval of this application cannot be granted until Alphapharm's 180-day generic drug exclusivity has expired and the Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, please submit a MINOR AMENDMENT – FINAL APPROVAL REQUESTED approximately 60 days prior to when you believe your application may be considered for final approval. Your amendment must provide:

1. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

2. a statement that no such changes have been made to the application since the date of tentative approval.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The amendment should be designated as a MINOR AMENDMENT in your cover letter. Before you submit the amendment, please contact Bonnie McNeal, Project Manager, at 301-827-5849, for further instructions.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

TENTATIVE APPROVAL